

# Election b/twn Product + Process Claims

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period to extend beyond the expiration of the patent, the owner or its agent may submit an application to the Commissioner of Patents and Trademarks for an interim extension of the patent term. If the Commissioner determines that, except for permission to market or use the product commercially, the patent would be eligible for a statutory extension of the patent term, the Commissioner shall issue to the applicant a certificate of interim extension for a period of not more than one year.

On November 13, 1995, Akzona Incorporated, owner of record in the Patent and Trademark Office of U.S. Patent No. 4,062,848, filed an application for interim extension of the term of this patent under 35 U.S.C. § 156(d)(5). The application states that the patent claims a compound comprising the active ingredient of the drug product "REMIFERON." The application states that the product is currently undergoing a regulatory review before the Food and Drug Administration for permission to market or use the product commercially. The original term of the patent expired on December 13, 1994. On December 5, 1994, the patent was granted a first interim extension under 35 U.S.C. § 156(d)(5) for a period of one year. Applicant now requests another interim extension of the term of the patent for a period of one year.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that the regulatory review period may extend beyond the date of expiration of the patent, as extended by the first interim extension, a second and final interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate. Accordingly, an interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,062,848 has been granted for a period of one year from the extended expiration date of the patent term in effect.

February 21, 1996

BRUCE A. LEHMAN  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks

## Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)

The purpose of this Notice is to provide guidance to Patent and Trademark Office personnel and to the public on the proper consideration of certain claims in light of *In re Ochiai*, 71 F. 3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, \*\* F.3d \*\*, 37 USPQ2d 1663 (Fed. Cir. 1996) and the passage of 35 U.S.C. § 103(b), which became effective November 1, 1995. *Ochiai*, *Brouwer* and § 103(b) relate to how process claims directed to making or using nonobvious products are to be treated.

The Court in *Ochiai* and *Brouwer* addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under the 35 U.S.C. § 103. Rather, § 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. To support a rejection under § 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In applying this test to the claims on appeal, the Court held that there simply was no suggestion or motivation in the prior art to make or use the nonobvious products to which the claims were limited and consequently overturned the rejections based upon § 103.

Interpreting a claimed invention as a whole requires consideration of all claim limitations. Thus, language in a process claim which recites making or using a nonobvious product must be treated as a material limitation, and a motivation to make or use the nonobvious product must be present in the prior art for a § 103 rejection to be sustained.

In light of *Ochiai* and *Brouwer*, Office personnel will consider all claim limitations when analyzing process claims which make or use nonobvious products under § 103. Office personnel will focus on treating claims as a whole and follow the analysis

set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).

Accordingly, to facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final. If the application was already under final rejection, the next Office action may be an advisory action.

35 U.S.C. § 103(b) is applicable to biotechnological processes only. Section 103(b) precludes a rejection of process claims which involve the use or making of certain nonobvious biotechnological compositions of matter under § 103(a). Section 103(b) requires that:

1. the biotechnological process and composition of matter be contained in either the same application or in separate applications having the same effective filing date;
2. both the biotechnological process and composition of matter be owned or subject to an assignment to the same person at the time the process was invented;
3. a patent issued on the process also contain the claims to the composition of matter used in or made by the process, or, if the process and composition of matter are in different patents, the patents expire on the same date;
4. the biotechnological process falls within the definition set forth in § 103(b); and
5. a timely election be made to proceed under the provisions of § 103(b).

In view of the Federal Circuit's decisions in *Ochiai* and *Brouwer*, an applicant's need to rely upon § 103(b) should be rare. Consequently, the Patent and Trademark Office will treat § 103(b) elections on a case-by-case basis by way of petition under 37 CFR 1.182. That petition must establish that all the requirements set forth in § 103(b) have been satisfied. An election will normally be considered timely if it is made no later than the earlier of (1) the payment of the issue fee, or (2) the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under 35 U.S.C. §§ 102 or 103.

In an application where at least one composition of matter claim has not been rejected under 35 U.S.C. §§ 102 or 103, a § 103(b) election may be made by submitting the petition and an amendment requesting entry of process claims which correspond to the composition of matter claim.

For applications pending on or after November 1, 1995, in which the issue fee has been paid prior to the date of this Notice, the timeliness requirement for an election under § 103(b) will be considered satisfied if the conditions of 37 CFR 1.312(b) are met. However, if a patent is granted on an application entitled to the benefit of § 103(b) without an election having been made as a result of error without deceptive intent, patentees may file a reissue application to permit consideration of process claims which qualify for § 103(b) treatment.

Any questions, comments or suggestions regarding petitions under 37 CFR 1.182 filed pursuant to this Notice should be directed to the Special Program Law Office, attention: Hiram Bernstein, Senior Legal Advisor. All other questions, comments or suggestions regarding this Notice should be directed to the Solicitor's Office, attention: Craig Kaufman, Associate Solicitor.

February 28, 1996

BRUCE A. LEHMAN  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks

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